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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,900	11/30/2001	Genichi Kakefuda	043753/241148 (5849-20A)	5699

826 7590 04/22/2003

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,900

Applicant(s)

KAKEFUDA ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claim 1-14 in Paper No. 6, filed 21 February 2003, is acknowledged. The traversal is on the ground(s) that the Examiner was in error to assert that the invention of Group II could not be used to make the transgenic plant of Group I, arguing that the specification discloses that the plant expression vector comprises the *Arabidopsis* AHAS small subunit promoter and a DNA sequence encoding an *Arabidopsis* small subunit AHAS protein (paragraph spanning pages 2-3 of the response). This is not found persuasive because MPEP § 808.01 clearly states that where they, the inventions, are not connected in design, operation or effect under the disclosure of the particular application under considerations, that restriction is proper. In the instant case, the isolated DNA encoding a eukaryotic AHAS small subunit protein is not connected in design, operation or effect with the promoter region of the *Arabidopsis* small subunit AHAS genomic DNA sequence. Clearly, the design, operation and effect of a coding sequence is distinct from a promoter sequence.

Applicant argument that the search required to examine both inventions would not be a serious burden is not found persuasive because the invention of Group I encompasses a broad genus of DNAs encoding a eukaryotic AHAS small subunit protein (page 3, 3rd paragraph of the response).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-21 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

3. This application contains claims 15-21 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. Parent application 09/426,568, filed 22 October, 1999, does not provide adequate support under 35 USC § 112, first paragraph, for the negative limitation in claim 1, claims 2-5 are all dependent upon claim

1. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

6. Applicant's claim for domestic priority under 35 U.S.C. § 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. § 112 for claims 1-5 of this application. Provisional application 60/106,239 does not provide adequate support under 35 USC § 112, first paragraph, for the negative limitation in claim 1, claims 2-5 are all dependent upon claim 1.

Information Disclosure Statement

7. The information disclosure statement filed 30 November 2001 has been considered, a signed copy is attached hereto.

Specification

8. The disclosure is objected to because of the following informalities: The Preliminary Amendment to the specification, filed 3 January 2002, is acknowledged, but parent application 09/426,568 has issued as US Patent 6,348,643. The priority statement at the first line of the specification must now be amended to reflect the status of the parent application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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10. Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, the phrase "a DNA sequence" at line 2 is unclear if said phrase is directed to an isolated DNA sequence or if Applicant intends to encompass insertion of a heterologous promoter expressible in a plant cell to be operably linked to the endogenous DNA sequence, in *Arabidopsis*, encoding a small subunit AHAS protein, hence it is unclear what the metes and bounds of the claim are.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated DNA sequence encoding a eukaryotic AHAS small subunit protein, wherein the DNA sequence is not isolatable from *Nicotiana plumbaginifolia* or maize, a plant expression vector comprising said isolated DNA sequence and a transgenic plant and progeny thereof comprising said plant expression vector.

Applicant describes an isolated DNA molecule encoding an AHAS small subunit protein having the sequence of SEQ ID NO: 1 that encodes the amino acid sequence of SEQ ID NO: 2, isolated from *Arabidopsis thaliana* (see pages 15-19 of the

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specification).

Applicant does not describe other isolated DNA molecules encoding a eukaryotic AHAS small subunit protein, not known in the art at the time of Applicant's invention.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, Applicant has only described a single species of the claimed genus/subgenus, and does not describe structural features common to the members of the claimed genus, only their function.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without

any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

In addition, Applicant has filed the instant application as a Continuation of Application 09/426,568, now US Patent 6,348,643, but the limitation in claim 1, "wherein said DNA sequence is not isolatable from *Nicotiana plumbaginifolia* or maize" does not have support in either the parent application or in provisional application 60/106,239 under 35 USC § 112, first paragraph for this limitation. Hence, claims 1-5 constitute new matter. Appropriate action is required.

13. Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA sequence encoding a AHAS small subunit protein having the sequence of SEQ ID NO: 1 or encoding the amino acid sequence of SEQ ID NO: 2, expression vectors comprising said isolated DNA sequence and transgenic plants comprising said expression vector, does not reasonably provide enablement for any DNA sequence encoding a eukaryotic AHAS small subunit protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated DNA sequence encoding a eukaryotic AHAS small subunit protein, wherein the DNA sequence is not isolatable from *Nicotiana plumbaginifolia* or maize, a plant expression vector comprising said isolated DNA sequence and a transgenic plant and progeny thereof comprising said plant expression

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vector.

Applicant teaches an isolated DNA molecule encoding an AHAS small subunit protein having the sequence of SEQ ID NO: 1 that encodes the amino acid sequence of SEQ ID NO: 2, isolated from *Arabidopsis thaliana* (see pages 15-19 of the specification).

Applicant does not teach other isolated DNA molecules encoding a eukaryotic AHAS small subunit protein, not known in the art at the time of Applicant's invention.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for isolating the claimed genus of DNA molecules encoding an AHAS small subunit protein from eukaryotic organisms. The instant claims encompass any DNA molecule encoding an AHAS small subunit protein from any eukaryotic organism, other than that from *Nicotiana plumbaginifolia* or maize that was known in the art at the time of Applicant's invention. Duggleby, in reference to isolating eukaryotic AHAS small subunit genes by homology, teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven in experiments designed to evaluate that function (1997, *Gene* 190:245-249, see

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page 248, left column, last paragraph). Applicant admits that association of large and small subunits, of AHAS proteins, appear to be highly specific, and that heterologous small and large AHAS subunit proteins do not interact properly (page 31, 2nd paragraph of the specification). This fact would additionally require one of skill in the art to identify and isolate the associated large subunit protein or encoding DNA sequence in order to determine function. Hence, given the limited guidance by Applicant, the breadth of the claims and the state of the prior art, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of eukaryotic DNA sequences, even those based on homology as taught by Duggleby, to identify those that encode a AHAS small subunit protein.

14. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to an isolated DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein, does not reasonably provide enablement for a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to a DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein that is endogenous to said transgenic plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to a DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein.

Applicant teaches a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to an isolated DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein.

Applicant does not teach a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to a DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein that is endogenous to said transgenic plant.

The teachings of *in re Wands* are discussed above. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The instant claim reads on insertion of a heterologous promoter expressible in a plant cell in operable linkage with an endogenous *Arabidopsis* AHAS protein encoding DNA sequence. Incorporation of heterologous DNA into a plant is random and would require extensive experimentation to insert a heterologous promoter DNA in operable linkage with a target endogenous coding sequence, specifically an *Arabidopsis* AHAS protein encoding DNA sequence. Applicant provides no guidance to insertion of a heterologous promoter DNA in operable linkage with a target endogenous coding

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sequence, specifically an *Arabidopsis* AHAS protein encoding DNA sequence.

Applicant provides no examples of a transgenic plant comprising the insertion of a heterologous promoter DNA in operable linkage with a target endogenous coding sequence, specifically an *Arabidopsis* AHAS protein encoding DNA sequence. Hence, given the quantity of experimentation necessary, the amount of guidance by Applicant and the absence of working examples of the invention as broadly claimed, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make a transgenic plant comprising a heterologous promoter DNA in operable linkage with a target endogenous coding sequence, specifically an *Arabidopsis* AHAS protein encoding DNA sequence.

Amendment of the instant claim to read -- operably linked to an isolated DNA sequence -- would obviate this rejection.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Abell *et al* (World Patent No. WO 98/37206 A1, published 27 August 1998).

Applicant claims an isolated DNA sequence encoding a eukaryotic AHAS small subunit protein wherein said DNA sequence is not isolatable from *Nicotiana plumbaginifolia* or maize, and a plant expression vector comprising said DNA sequence.

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Abell teaches the DNA sequences encoding an AHAS small subunit protein isolated from maize (SEQ ID NO: 1, page 29) and isolated from *Nicotiana plumbaginifolia* (SEQ ID NO: 4, pages 30-32) and expression vectors comprising said DNA sequences (see Figures 1 and 2). Abell teaches that expression can include, but is not limited to, plants transformed with an AHAS small subunit protein (see page 5, lines 10-18).

The instant claims are *prima facie* obvious because Abell has taught two species within the genus and thus the species taught by Abell renders the claimed genus obvious to one of ordinary skill in the art at the time of Applicant's invention. Abell motivates one of ordinary skill in the art to isolate other nucleic acid fragments encoding the small subunit of a plant acetolactate synthase (syn. AHAS) (see claim 1). In addition, Abell teaches one of ordinary skill in the art how to isolate and identify nucleic acid fragments from plant that encode the small subunit of a plant acetolactate synthase (see Example 1 on pages 11-14). Given the success of Abell in isolating two species of plant AHAS small subunit protein encoding nucleic acids and the guidance by Abell on how to isolate said nucleic acids, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in isolating other plant AHAS small subunit protein encoding nucleic acids.

See *In re Slayter*, 125 USPQ 345, 347 (CCPA 1960) which teaches that it is well settled that a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus; in other words, whatever would infringe if subsequent will anticipate if prior.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

18. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 23 of U.S. Patent No. 6,348,643. Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated DNA sequence encoding a eukaryotic/plant AHAS small subunit protein at claims 1 and 2, the plant expression vector comprising said isolated DNA sequence at claim 3 and the transgenic plant and progeny thereof comprising said vector at claims 4 and 5 of the instant application are obvious in view of the isolated DNA sequence encoding an *Arabidopsis* AHAS small subunit protein at claim 1, the plant expression vector comprising said isolated DNA sequence at claim 4 and the transgenic plant at claim 23 of the '643 patent, respectively. The isolated DNA sequence encoding the amino acid sequence set forth in SEQ ID NO: 2 at claim 6, the plant expression vector comprising said isolated DNA sequence at claim 7 and the transgenic plant and progeny thereof at claims 8 and 9 of

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the instant application are obvious in view of the isolated DNA sequence encoding an *Arabidopsis* AHAS small subunit protein at claim 1, the plant expression vector comprising said isolated DNA sequence at claim 4 and the transgenic plant at claim 23 of the '643 patent, respectively. The plant expression vector comprising the DNA sequence set forth in SEQ ID NO: 1 at claim 10 and the transgenic plant and progeny plant at claims 11 and 12 comprising said vector of the instant application are obvious in view of the isolated DNA sequence comprising the sequence set forth in SEQ ID NO: 1 at claim 2, the plant expression vector at claim 4 and the transgenic plant at claim 23 of the '643 patent. The transgenic plant at claim 13 of the instant application is obvious in view of the transgenic plant of claim 23 of the '643 patent. In each instance above, the claims of the instant application would grant the unjustified or improper timewise extension of the "right to exclude" granted by a patent directed to claims 1-14 of the instant application in view of claims 1, 2, 4 and 23 of the '643 patent, in particular an isolated DNA sequence encoding an *Arabidopsis* AHAS small subunit protein and specifically an isolated DNA sequence comprising the sequence set forth in SEQ ID NO: 1.

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Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "David H. Kruse". The signature is written in a cursive, flowing style with a large initial "D".

David H. Kruse, Ph.D.
21 April 2003